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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/846,637	04/30/2001	Michael C. Jensen	24751-2502	4845

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EXAMINER

PAK, YONG D

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/846,637

Applicant(s)

JENSEN, MICHAEL C.

Examiner

Yong D Pak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 73,74,142,143,219,220,234,235,248 and 249 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 73-74, 142-143, 219-220, 234-235 and 248-249 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The amendment filed on November 14, 2004, amending claims 73-74 and canceling claims 190-191, 206-207, 260-261 and 270-285, has been entered.

Claims 73-74, 142-143, 219-220, 234-235 and 248-249 are pending and are under consideration.

Response to Arguments

Applicant's amendment and arguments filed on November 14, 2004, have been fully considered and are deemed to be persuasive to overcome the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 103

Claims 73-74, 142-143, 219-220, 234-235 and 248-249 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Farazi et al. in view of Lightfoot et al. and Roelant et al.

Applicants argue that Farazi does not teach the use of mutant IMPDH in anti-infective chemotherapy and does not teach or suggest the introduction of IMPDH

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mutants into a cell to selectively proliferate cells. The instant invention is not drawn to a method of using mutant IMPDH in anti-infective chemotherapy but a method of selecting for cells comprising mutant IMPDH which are resistant to IMPDH. Farazi teaches that mutants of human IMPDH are resistant to inhibitors of wildtype IMPDH (abstract and page 961). Farazi also teaches that that mutant IMPDH which are resistant to IMPDH inhibitors can be identified by screening for cells which are able to grow the presence of inhibitors of IMPDH (page 961, last paragraph). The only difference between the reference of Farazi et al. and the instant invention is the mutant IMPDH.

Wildtype IMPDH and the mutant IMPDH of the instant invention, SEQ ID NO:4, is different at residues 190, 191, 333 and 351. However, Farazi et al. teaches that the wildtype sequenced by Collart et al. was incorrect, and that wild type human IMPDH II naturally has an alanine at residue 190 and Glycine at residue 191 (page 962, third full paragraph). Therefore, the only difference between the mutant of the instant invention and wild type IMPDH II is at residues 333 and 351. Lightfoot et al. (form PTO-1449) teaches a mutant mouse IMPDH having resistance to MPA (abstract). The mutant IMPDH of Lightfoot et al. has two point mutations, Thr-333-Ile and Ser-351-Tyr (abstract). Human wild type IMPDH type II also has a Thr at residue 333 and Ser at residue 351. The two mammalian enzymes are also highly homologous.

Therefore, one of ordinary in the skill in the art would have been motivated to make mutations at residues 333 and 351 and expose cells comprising said mutant to IMPDH inhibitors, along with a control (cells comprising wildtype IMPDH), and select cells which are able to grow or proliferate in the presence of an IMPDH inhibitor by

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using cell proliferation methods well known in the art such as that of Roelant et al. or Farazi. The motivation of making mutations at residues 333 and 351 to the IMPDH of Farazi is to make and screen for other mutant human IMPDH which are resistant to IMPDH inhibitors. The motivation of performing the cell proliferation assay is to determine if said mutant IMPDH are resistant to IMPDH inhibitors. One of ordinary skill in the art would have had a reasonable expectation of success since Farazi and Lightfoot teaches mutant IMPDH which are resistant to IMPDH inhibitors and Farazi teaches mutant IMPDH which are resistant to IMPDH inhibitors can be identified by screening for cells comprising mutant IMPDH which are able to grow in the presence of IMPDH inhibitors.

None of the claims are allowable.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Yong D. Pak
Patent Examiner



PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
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